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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,326	03/08/2001	Szu-Min Lin	JOHNA.25C1CP1	5267
27777	7590	01/20/2004	EXAMINER	
<p>PHILIP S. JOHNSON JOHNSON &amp; JOHNSON ONE JOHNSON &amp; JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003</p>				MCKANE, ELIZABETH L
ART UNIT		PAPER NUMBER		
				1744

DATE MAILED: 01/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/802,326	LIN ET AL.
	Examiner Leigh McKane	Art Unit 1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-44 is/are pending in the application.  
 4a) Of the above claim(s) 17-44 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-16 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
 a) The translation of the foreign language provisional application has been received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

*Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-16, drawn to a method and system for sterilizing a lumen employing the device of Figure 11, classified in class 422, subclass 33.
  - II. Claims 17-25, drawn to a system for sterilizing a lumen employing the device of Figure 9, classified in class 422, subclass 33.
  - III. Claims 26-32, drawn to a method for sterilizing a lumen employing the device of Figure 7, classified in class 422, subclass 33.
  - IV. Claims 33-44, drawn to a method and system for sterilizing a lumen employing the device of Figure 8, classified in class 422, subclass 33.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, as clearly disclosed by the specification.
3. During a telephone conversation with Mr. Andrew Farmer on 6 January 2004 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-16. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17-44 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1-7 and 9-15 are rejected under 35 U.S.C. 102(a) & (e) as being anticipated by Kowanko (U.S. Patent No. 6,162,395).

Kowanko teaches a system and method for sterilizing lumens wherein the lumen **40** and a container **46** are enclosed in a chamber **50** and wherein the container **46** has a permeable interface **48** across which the lumen is placed such that a first end **54** of the lumen is in the

container and the second end **52** is in the chamber. See Figure 2. In use, a sterilant is introduced into the evacuated chamber from a source outside of the chamber, the pressure increased, and the germicide flows from the chamber through the lumen into the container. See col.8, line 35 to col.9, line 21. Thereafter, the evacuation and pressurization steps may be repeated. Finally, a purge gas is used to remove the sterilant and the chamber vented. The sterilant may be hydrogen peroxide. See col.7, lines 9-11. In a similar embodiment shown in Figure 4, the container **64** may have a communication port **70** that is different from the interface opening **76**.

7. Claims 1-4, 6, 8, 10, 11, 13, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Fournier (U.S. Patent No. 6,365,103 B1).

Fournier teaches a method and apparatus for the sterilization of lumen devices (endoscopes). As illustrated in Figure 2b, a lumen **210** and a container **235** are enclosed within a chamber **10**. The lumen **210** is positioned across an interface **240** of the container such that a first end is in the container and a second end is in the chamber. In operation, the pressure is reduced within the chamber and a sterilant gas introduced therein. The pressure is increased and the gas is driven through the lumen into the container. See col.7, lines 31-57. The steps of evacuation and pressurization are repeated as desired, after which the chamber is vented. The interface opening is constructed of an elastomeric septum (col.7, lines 59-63), which is intrinsically adjustable for different sized lumens.

*Conclusion*

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Wednesday (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1275. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1700.

*Leigh McKane*  
**Leigh McKane**  
**Primary Examiner**  
**Art Unit 1744**

elm  
12 January 2004